No. 89-243

In The
Supreme Court of the United States
October Term, 1989

ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

MOTION AND BRIEF FOR AMICUS CURIAE AMERICAN STERILIZER COMPANY IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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Pursuant to Rule 36.1 of this Court, American Sterilizer Company (AMSCO) respectfully moves this Court for leave to file the attached brief *amicus curiae* in support of the petition for certiorari. Consent of Respondent was denied although Respondent indicated that, if supplied with a copy of the brief, it would further consider Movant's request. A copy of the brief, when completed, was telecopied to Respondent on 6 September. Consent was not received by the end of business that day, which was the deadline established by the printer for printing the instant motion.

AMSCO is a manufacturer of various types of capital equipment, such as sterilizers, used in the health care

industry and which are regulated by the Food and Drug Administration. It is AMSCO's position that the decision below has:

(i) improperly expanded the narrow exception to patent infringement set forth in 35 U.S.C. §271(e)(1);

(ii) seriously interfered with the patent rights of capital equipment manufacturers such as AMSCO; and

(iii) raised serious Fifth Amendment questions.

AMSCO's views will be helpful to the Court in understanding the tremendous impact of the Federal Circuit's decision upon capital equipment manufacturers which, heretofore, were not believed to be encompassed within 35 U.S.C. §271(e)(1).

Respectfully submitted,

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Dated: 9 September 1989

QUESTION PRESENTED

American Sterilizer Company adopts the following question presented by Petitioner Eli Lilly and Company.

35 U.S.C. §271(e)(l) provides that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of *drugs or veterinary biological products"* (emphasis added).

The question presented is:

Whether the Court of Appeals erred as a matter of law by expanding the patent infringement exemption of 35 U.S.C. §271(e)(1) beyond "drugs" and "veterinary biological products" to encompass, and thereby to erode patent protection for, medical devices, food additives, color additives, and all other FDA-regulated, nondrug products?

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American Sterilizer Company (AMSCO) files this *amicus curiae* brief in support of the petition of Eli Lilly and Company (Lilly) for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit, entered in the above-captioned proceeding on March 29, 1989.

INTEREST OF THE AMICUS CURIAE

AMSCO is a capital equipment manufacturer. Some of its equipment is regulated by the Food & Drug Administration (FDA). The decision of the court below has dramatically expanded the narrow exception to patent infringement enacted by Congress in 35 U.S.C. §271(e)(1). Such a broad interpretation of that statute has seriously eroded AMSCO's patent rights and the rights of all such capital equipment manufacturers. The errosion of AMSCO's patent rights is evidenced by the actions of the defendant in a civil action now pending in the Northern District of Texas, Fort Worth Division, in which AMSCO sued for patent infringement. (Civil Action No. CA-4-89-238-K). The defendant has raised 35 U.S.C. §271(e)(1), as interpreted by the Federal Circuit, as a defense. Thus, AMSCO has a compelling interest in having this Court correct the erroneous decision below and restoring to it the full measure of protection afforded by its patents.

ARGUMENT

A. The Decision Of The Court Of Appeals Is Clearly Erroneous

The Federal Circuit had before it a legal issue involving statutory interpretation. Surprisingly, the decision is not based on the language of the statute because "each [party] has put forth equally plausible interpretations of section §271(e)(1), which to us means the language is fraught with ambiguity." *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402, 405 (Fed. Cir. 1989). Faced with that "ambiguous" language, the court failed to look to the legislative history for guidance because "each side has been

able to highlight general statements in the legislative history which allegedly support their own reading of §271(e)(1)." 872 F.2d at 405.

Rather than rely on standard canons of statutory construction, such as analyzing the language of the statute and the legislative history, the court took a different tack. The court started off well enough with the proposition that "§271(e)(1) was added to overrule this court's decision in *Roche* [*Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984)]." 872 F.2d at 406. However, the court erred when it failed to review the legislative history to ascertain what *Congress* thought the *Roche* decision meant. Instead, the court substituted *its* interpretation of the *Roche* decision. By relying on its version of the meaning of *Roche* instead of reviewing the legislative history to ascertain Congress' understanding of *Roche*, the court engaged in improper legislation in the guise of statutory interpretation.

To support the conclusion that it reached, the court stated that "[n]o persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation." 872 F.2d at 406. That statement belies a fundamental misunderstanding of the ways that drugs and medical devices are approved. Generic drug approval is obtained by performing a series of tests to establish bioequivalency. Because medical devices encompass a wide variety of devices from implantable cardiac pacemakers, to sterilizers, to snake bite kits, there is no one, well defined, series of tests which must be satisfied. The tests may involve, for example, placing a large piece of capital equipment at several potential customers' sites and allowing that

piece of equipment to be operated over a period of several months. During that period, salesmen as well as technical people continually call upon the potential customers. That situation is substantially different from bioequivalency testing which may be carried out in the generic drug manufacturer's own laboratories. Such differences could well be the basis for Congress' creation of an exception for drugs but not medical devices.

B. The Court's Decision Has Serious And Far Reaching Constitutional Implications

In enacting §271(e)(1), Congress was very concerned with the constitutional ramifications of creating an exception to patent infringement. Congress carefully reviewed those constitutional ramifications in the context of *bioequivalency* testing. In that narrow context, Congress concluded that the nature of the interference was not substantial. H. R. Rep. No. 857, 98th Cong., 2d Sess. Part 2, *reprinted in* 1984 U.S. Code Cong. & AD. News 2647, 2692. No such constitutional analysis has been performed with respect to medical devices although the Federal Circuit's interpretation of §271(e)(1) purports to include medical devices within the exception of that section. Because of the wide range of devices apparently now falling within the scope of §271(e)(1), no court is in a position to envision all of the ramifications of such a sweeping change in the law. By making a whole host of heretofore infringing activities apparently no longer infringing activities, serious constitutional questions have been raised. Such a sweeping change should be left to Congress where capital equipment manufacturers will have an opportunity to state their case.

CONCLUSION

For the foregoing reasons, *amicus curiae* respectfully requests that this Court grant the Petition for Certiorari.

Respectfully submitted,

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